IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION NO. 1:25-CV-00368

UNITED THERAPEUTICS CORPORATION, *Plaintiff*, v. LIQUIDIA TECHNOLOGIES, INC., *Defendant*.	**FILED UNDER SEAL** **HIGHLY CONFIDENTIAL**

PLAINTIFF UNITED THERAPEUTICS CORPORATION'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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TABLE OF ABBREVIATIONS

Abbreviation	Full Name
’782 patent	U.S. Patent No. 11,357,782
’793 patent	U.S. Patent No. 10,716,793
’793 IPR	*Inter partes* review proceeding regarding the ’793 patent
D.I.	Docket Index
DPI	Dry Powder Inhaler
Liquidia	Liquidia Technologies, Inc.
Liq. P.R.	Liquidia Press Release
mcg	microgram
Nathan Decl.	Declaration of Steven D. Nathan, M.D. in Support of Plaintiff’s Motion for a Temporary Restraining Order and Preliminary Injunction (concurrently filed herewith)
NDA	New Drug Application
PAH	Pulmonary arterial hypertension
PH	Pulmonary hypertension
PH-ILD	Pulmonary hypertension associated with interstitial lung disease
PI	Preliminary Injunction
PTAB	Patent Trial and Appeal Board
POSA	Person of Ordinary Skill in the Art
Selck Decl.	Declaration of Frederic Selck, Ph.D., in Support of Plaintiff’s Motion for a Temporary Restraining Order and Preliminary Injunction (concurrently filed herewith)
TRO	Temporary Restraining Order
UTC	United Therapeutics Corporation
UTC P.R.	UTC Press Release

TABLES OF EXHIBITS

EXHIBITS TO THE COMPLAINT IN THIS ACTION

ECF No.	Title	Short Title
ECF 1-1 (Ex. A)	U.S. Patent No. 11,357,782	'782 patent
ECF 1-2 (Ex. B)	Proposed Yutrepia™ Label, as filed in No. 24-cv-2428 (D.D.C.) ECF No. 78-2	Yutrepia™ Label
ECF 1-3 (Ex. C)	*U.S. FDA Grants Tentative Approval of YUTREPIA™ (treprostinil) Inhalation Powder for Patients with Pulmonary Arterial Hypertension (PAH) and Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD)*, Liquidia Corp. (Aug. 19, 2024), https://www.liquidia.com/news-releases/news-release-details/us-fda-grants-tentative-approval-yutrepiatm-treprostinil	Liq. P.R. 8-19-24
ECF 1-4 (Ex. D)	*Liquidia Corporation Announces FDA Acceptance of New Drug Application Resubmission for YUTREPIA™ (treprostinil) Inhalation Powder*, Liquidia Corp. (Mar. 28, 2025), https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-announces-fda-acceptance-new-drug	Liq. P.R. 3-28-25
ECF 1-5 (Ex. E)	Transcript of Liquidia (LQDA) Gears Up for FDA Approval of Yutrepia | Needham 2025, YOUTUBE, https://www.youtube.com/watch?v=_y5it02b88E	Apr. 2025 Jeffs Tr.
ECF 1-6 (Ex. F)	*Liquidia Provides Update on Clinical Pipeline Targeting PAH and PH-ILD*, Liquidia Corp. (Jan. 5, 2024), https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-clinical-pipeline-targeting-pah-and-ph	Liq. P.R. 1-5-24

EXHIBITS TO THIS MEMORANDUM

Exhibit No.	Title	Short Title
Exhibit 1	*Therapeutic Areas*, United Therapeutics Corp., https://www.unither.com/research-and-medicine/therapeutic-areas (last visited May 8, 2025)	UTC, *Therapeutic Areas*
Exhibit 2	*United Vision*, United Therapeutics Corp., https://www.unitedbyph.com/ (last visited May 8, 2025)	UTC, *United Vision*
Exhibit 3	*FDA Approves TYVASO (Treprostinil) Inhalation Solution for the Treatment of Pulmonary Arterial Hypertension*, United Therapeutics Corp. (July 31, 2009), https://ir.unither.com/press-releases/2009/30-07-2009	UTC P.R. 7-31-09
Exhibit 4	*United Therapeutics Announces FDA Approval of Tyvaso DPI™*, United Therapeutics Corp. (May 24, 2022), https://ir.unither.com/press-releases/2022/05-24-2022	UTC P.R. 5-24-22
Exhibit 5	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-755-RGA, D.I. 436 (D. Del. Sept. 9, 2022)	Final Judgment
Exhibit 6	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-755-RGA, D.I. 461 (D. Del. Dec. 26, 2023)	Mot. to Amend Judgment
Exhibit 7	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-755-RGA, D.I. 480 (D. Del. Mar. 28, 2024)	Amended Judgment
Exhibit 8	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-cv-975-RGA, D.I. 45 (D. Del. Mar. 15, 2024)	Scheduling Order
Exhibit 9	*Liquidia Techs., Inc. v. FDA*, No. 24-cv-2428-TJK, D.I. 95 (D.D.C. Feb. 27, 2025)	Mem. Op.
Exhibit 10	*Liquidia Techs., Inc. v. FDA*, No. 24-cv-2428-TJK, D.I. 104 (D.D.C. May 2, 2025)	Dismissal Op.

Exhibit 11	*Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. 25-cv-299-TDS, D.I. 1 (M.D.N.C. Apr. 21, 2025)	Liquidia Patent Complaint
Exhibit 12	U.S. Patent No. 10,898,494	'494 patent
Exhibit 13	U.S. Patent No. 10,716,793	'793 patent
Exhibit 14	*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 2021CVS4094, D.I. No. 155 (N.C.B.C. Sept. 7, 2023)	Trade Secrets Complaint
Exhibit 15	File History of U.S. Patent No. 11,357,782	'782 patent file history
Exhibit 16	*Liquidia Corporation Reports Full Year 2024 Financial Results and Provides Corporate Update*, Liquidia Corp. (Mar. 19, 2025), https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-reports-full-year-2024-financial-results	Liq. P.R. 3-19-25
Exhibit 17	Liquidia Corp., Presentation at 42nd Annual J.P. Morgan Healthcare Conference (Jan. 10, 2024)	Jan. 10, 2024 J.P. Morgan Transcript
Exhibit 18	Robert Roscigno, *Pharmacokinetics and Tolerability of LIQ861, A Novel Dry-Powder Formulation of Treprostinil*, 10 Pulmonary Circulation 1 (Nov. 1, 2020), https://doi.org/10.1177/2045894020971509	Roscigno 2020a
Exhibit 19	Deposition of David Barton, *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-cv-975-RGA (D. Del. Nov. 14, 2024)	Barton Tr.
Exhibit 20	Roscigno, R. et al., *Pharmacokinetics and Tolerability of LIQ861, a Novel Dry-Powder Formulation of Treprostinil*, 10 PULMONARY CIRCULATION, Nov. 1, 2020, 1-9	Roscigno 2020b
Exhibit 21	Liquidia Corp, FQ1 2025 Earnings Call Transcript (May 8, 2025)	May 8, 2025 Earnings Call Tr.

INTRODUCTION

Plaintiff United Therapeutics Corporation ("UTC") respectfully submits this brief in support of its Motion for a Temporary Restraining Order ("TRO") and Preliminary Injunction ("PI"). UTC requests this emergency relief to temporarily preserve the status quo while the parties brief, and the Court considers, UTC's request for a preliminary injunction. UTC files this Motion under extraordinary circumstances: Defendant Liquidia Technologies, Inc. ("Liquidia") has made clear that in just weeks, it plans to launch its proposed product, Yutrepia™, a copy of UTC's Tyvaso® and Tyvaso DPI® products despite the existence of UTC's patent rights. Exhibit 17 (Jan. 10, 2024 J.P. Morgan Transcript), 6. In its May 8, 2025 earnings call, Liquidia highlighted its substantial planning and the absence of any "legal barriers barring Yutrepia™'s potential final approval." In so doing, Liquidia confirmed it will release an infringing product that will irreparably harm UTC. With this imminent launch, a controversy exists between the parties regarding whether Liquidia will be permitted to induce infringement of UTC's U.S. Patent No. 11,357,782 ("the '782 patent," ECF 1-1). Accordingly, UTC now seeks the equitable protection of this Court and a declaration that using Yutrepia™ will infringe the '782 patent under 35 U.S.C. § 271(b). *See* ECF 1 (Complaint), ¶¶56-62 (Count II).

UTC's Tyvaso® and Tyvaso DPI® products are life-changing medications for patients with pulmonary hypertension, a rare and extremely severe illness involving elevated blood pressure in the lungs. The '782 patent generally covers using an inhaled dry powder formulation of treprostinil, administered in specific ways, to treat pulmonary

hypertension. Yutrepia™ is a dry powder formulation of treprostinil that uses UTC's methods of treatment; when Liquidia launches its product, it will infringe and irreparably harm UTC. Accordingly, UTC respectfully requests that this Court restrain Liquidia's attempt to trespass on UTC's intellectual property.

STATEMENT OF FACTS

UTC develops innovative treatments for pulmonary hypertension. Pulmonary hypertension ("PH") is a debilitating and often fatal disease characterized by elevated blood pressure in the lungs. Nathan Decl. ¶50. While PH always involves elevated blood pressure, the underlying causes and treatments vary. *Id.* ¶¶52-57. There are different varieties of PH, including pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). *Id.*

UTC, located in Research Triangle Park, develops and commercializes products for patients with chronic and life-threatening conditions, including PH. *See generally* Exhibit 1 (UTC, *Therapeutic Areas*). One therapy for PH is treprostinil, which lowers blood pressure in the lungs and improves patients' ability to walk and go about the activities that most people take for granted. Nathan Decl. ¶¶58-61. Following extensive research and development; risky, expensive clinical trials; and FDA approval; UTC currently markets multiple forms of treprostinil: an intravenous or subcutaneous infusion (Remodulin®); an oral, extended-release tablet (Orenitram®); an inhaled nebulized solution (Tyvaso®); and an inhaled dry powder (Tyvaso DPI®). Exhibit 2 (UTC, *United Vision*). UTC's efforts to

research and develop innovative treprostinil-based therapies have led to multiple patents, including the '782 patent. ECF 1-1.

FDA approved Tyvaso®, the first inhaled treprostinil therapy, for treatment of PAH in 2009. Exhibit 3 (UTC P.R. 7-31-09). Tyvaso® is administered with a nebulizer, a powered device that emits treprostinil solution as a fine mist for oral inhalation. *Id.* Later, in 2022, FDA approved Tyvaso DPI®, the first inhaled dry powder formulation of treprostinil, for PAH and PH-ILD. Exhibit 4 (UTC P.R. 5-24-22). Tyvaso DPI® is administered using a dry powder inhaler ("DPI"), a breath-powered device that emits the dry powder as airborne particles for inhalation. Providing a dry powder formulation option benefitted patients, as a dry powder inhaler can be a smaller, more convenient device than a nebulizer. *Id.*

Liquidia seeks to launch a follow-on PH treatment. Liquidia, based in Morrisville, NC, currently sells a generic version of intravenous treprostinil in cooperation with Sandoz, and does not have any innovative products of its own. Exhibit 16 (Liq. P.R. 3-19-25), 1-2. Following on UTC's success, in 2020, Liquidia sought FDA approval to market a dry powder inhaler ("DPI") version of treprostinil, Yutrepia™, for PAH. Nathan Decl. ¶78. Rather than conduct its own clinical trials on efficacy, Liquidia relied on UTC's Tyvaso® clinical data and conducted only studies sufficient to satisfy the FDA that Yutrepia™ would behave the same in patients as UTC's Tyvaso®. Nathan Decl. ¶84.

Other Litigation Between the Parties. After Liquidia first sought approval, UTC sued to enforce its patent rights in the District of Delaware, resulting in a finding that

"Liquidia's proposed LIQ861[, Yutrepia™,] product will induce infringement of claims 1, 4, 6, 7, and 8 of" UTC's U.S. Patent No. 10,716,793 ("the '793 Patent", Exhibit 13). Exhibit 5 (Final Judgment). The Federal Circuit affirmed. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360 (Fed. Cir. 2023). However, in an *inter partes* review ("the '793 IPR"), the Patent Trial and Appeal Board ("PTAB") found the '793 patent's asserted claims unpatentable. Exhibit 6 (Mot. to Amend Judgment); Exhibit 7 (Amended Judgment). The '793 patent is in the same family as the '782 patent but has different claims.

Based on Liquidia's drug application and reliance on UTC's Tyvaso® data, the parties are also currently litigating Liquidia's infringement of U.S. Patent No. 11,826,327, which claims a method of using inhaled treprostinil to improve exercise capacity in a specific patient population: patients with PH-ILD. Trial is scheduled for June 23-25, 2025. Exhibit 8 (Scheduling Order).[1]

UTC and Liquidia have also engaged in litigation in the District Court for the District of Columbia regarding the FDA's handling of Liquidia's New Drug Application ("NDA"). *See* Exhibit 9 (Mem. Op.) (affirming UTC's regulatory exclusivity). On May 2, 2025, the Court dismissed UTC's claims in that case. Exhibit 10 (Dismissal Op.).

Finally, on April 21, 2025, Liquidia sued UTC in this Court asserting U.S. Patent No. 10,898,494 ("the '494 patent") relating to administering treprostinil as a dry powder. Exhibit 11 (Liquidia Patent Complaint). Liquidia's '494 patent shares a common inventor

[1] UTC moved for a preliminary injunction, which the Court denied. 2024 WL 2805082. At that time, Yutrepia™ did not have a certain launch date. *Id.*

with UTC's '782 patent: Robert Roscigno. Exhibit 12 ('494 patent), 1. Roscigno was a UTC employee before he joined Liquidia, and UTC alleges in a pending trade-secret action in North Carolina state court that he misappropriated UTC's trade secrets to assist Liquidia in developing Yutrepia™. *See* Exhibit 14 (Trade Secrets Complaint).

The '782 patent claims an innovative method of treating PH. UTC filed the application that matured into the '782 patent on September 27, 2021, but it claims priority back to May 15, 2006. Exhibit 15 ('782 patent file history), 1, 2. In 2006, there were no approved inhaled formulations of treprostinil available, of any form—inhaled solution or dry powder. Nathan Decl. ¶58.

Prosecution of the '782 patent recognized its novelty over UTC's other patents and the prior art. To overcome a non-final rejection based on obviousness (Exhibit 15, 18-30). UTC and the Patent Examiner discussed "the unexpected results associated with the inhaled drug versus the teaching in the art." *Id.*, 31. After consideration of the prior art and arguments cited in the '793 IPR to that date (*id.*, 32), the Patent Office allowed the pending claims, stating "the claimed method of dosing a dry powder, in at least 15 micrograms to 90 micrograms of treprostinil delivered in 1 to 3 breaths, with at least 5 micrograms … per breath, wherein administration of additional single event dose in the same manner occurs at least 3 hours later is not obvious … as the method is not predictable." *Id.*, 47. The '782 patent issued on June 14, 2022, and expires on May 14, 2027. *Id.*, 50.

Liquidia plans to launch Yutrepia™ despite infringing the '782 patent. Liquidia has undertaken substantial preparation to launch Yutrepia™ "for both PAH and

PH-ILD" indications as soon as possible upon final approval by the FDA, which is expected by May 24, 2024. ECF 1-5 (Apr. 2025 Jeffs Tr.), 8:19-9:12; ECF 1-4 (Liq. P.R. 3-28-25); Exhibit 16; Exhibit 21 (May 8, 2025 Earnings Call Tr.) at 5, 11. And Liquidia has stated that it intends to launch despite being aware of UTC's patents. *Id.* Liquidia's CEO has even indicated that Liquidia will risk significant damages by launching Yutrepia™ as soon as possible with only enough cash in hand for a "bridge" to profitability. Exhibit 17, 8, 10.

Facing Liquidia's determination to come to market and irreparably harm UTC by infringing on its patent rights, UTC now seeks the protection of this Court.

QUESTION PRESENTED

Whether the Court should enter a temporary restraining order and preliminary injunction to prevent Liquidia from launching Yutrepia™ and infringing the '782 patent, causing UTC irreparable harm.

LEGAL STANDARD

"To obtain a preliminary injunction, a party must establish likelihood of success on the merits, likelihood it will suffer irreparable harm absent preliminary relief, the balance of equities tips in its favor, and an injunction is in the public interest." *Natera, Inc. v. NeoGenomics Lab'ys, Inc.*, 106 F.4th 1369, 1375 (Fed. Cir. 2024) (applying Fourth Circuit law).

The Court may issue "a TRO to preserve the status quo until a hearing on a motion for preliminary injunction can be held." *Advanced Instructional Sys., Inc. v. Competentum*

USA, Ltd., 2015 WL 7575925, at *2 (M.D.N.C. Nov. 25, 2015). TROs are governed by the same legal standards as preliminary injunctions. *Green v. ABC Companies*, 702 F. Supp. 3d 418, 423 n.1 (W.D.N.C. 2023).

ARGUMENT

UTC respectfully requests the Court temporarily restrain and preliminarily enjoin Liquidia from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling Liquidia's Yutrepia™ in the United States pending resolution of this motion and trial. 35 U.S.C. § 283; Fed. R. Civ. P. 65. Yutrepia™ will infringe the '782 patent. Allowing Liquidia to launch Yutrepia™ before the Court decides this motion and before trial will irreversibly change the market, irreparably harming UTC. UTC satisfies the standard for a temporary restraining order and preliminary injunction, as each factor weighs in UTC's favor, and this Court should grant relief.

I. UTC Is Likely to Succeed on the Merits

To carry its burden, UTC need show only that the launch of Liquidia's product will likely induce direct infringement by those using the product, and that Liquidia cannot raise a substantial question as to invalidity, considering that Liquidia will bear the burden of showing invalidity by clear and convincing evidence at trial. *Natera*, 106 F.4th at 1376 (Fed. Cir. 2024); *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 109 (2011); *Real Time Med. Sys., Inc. v. PointClickCare Techs., Inc.*, 131 F.4th 205, 223 (4th Cir. 2025) ("[T]he burdens at the preliminary injunction stage track the burdens at trial—meaning, for

example, defendants must shoulder the burden of proving an affirmative defense, even at the preliminary-injunction stage.").

A. UTC Has Standing

Liquidia has obtained tentative approval to market Yutrepia™ and has trumpeted its intention to launch Yutrepia™ by May 24, 2025, the day UTC's regulatory exclusivity expires. *Supra* at 3, 5-6. Because this will irreparably harm UTC, this Court has jurisdiction over the controversy now. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997) ("A patentee may seek a declaration that a person will infringe a patent in the future" and the equitable protection of the court). Indeed, "a party seeking injunctive relief is not required to wait until the harm has actually occurred to seek relief. It is the present threat of irreparable harm that this Court must consider." *Fairfield Resorts, Inc. v. Fairfield Mountains Prop. Owners Ass'n, Inc.*, 2006 WL 2524188, at *4 (W.D.N.C. Aug. 29, 2006) (quotation marks omitted). Liquidia's impending launch is just such a present threat to UTC. *Infra* § II. "In this setting, where it is clear that the defendant[] intend[s] to sell" its infringing drug product, "the Court has jurisdiction to address [UTC]'s declaratory judgment claim brought under sections 271(a), (b), and (c)." *Allergan, Inc. v. Teva Pharms. USA, Inc.*, 2017 WL 3676745, at *3 n.1 (E.D. Tex. Aug. 25, 2017) (Bryson, J.).

B. UTC Will Likely Succeed in Proving Infringement of the '782 Patent

"An assessment of the likelihood of infringement, like a determination of patent infringement at a later stage in litigation, requires a two-step analysis. First, the court

determines the scope and meaning of the patent claims asserted …. [Second,] the properly construed claims are compared to the allegedly infringing" product. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003) (quotation marks omitted). UTC will show that Liquidia infringes the '782 patent. If Liquidia is permitted to launch, patients and healthcare providers using Yutrepia™ will directly infringe, and Liquidia will be liable for their infringement.

The first step of the infringement analysis is determining the meaning of the claims. *Oakley*, 316 F.3d at 1339. Claim 1 recites:

> [1-a] A method of treating pulmonary hypertension comprising:
>
> [1-b] providing an inhalation device for treating pulmonary hypertension
>
> [1-c] comprising a powder formulation of treprostinil or a pharmaceutically acceptable salt thereof
>
> [1-d] and a dry powder inhaler configured to administer [a] single event dose of the powder formulation comprising treprostinil or a pharmaceutically acceptable salt thereof,
>
> [1-e] wherein the single event dose comprises at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof
>
> [1-f] delivered in 1 to 3 breaths,
>
> [1-g] wherein the dry powder inhaler is configured to administer the entire single event dose in less than 5 minutes with at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof being inhaled per breath
>
> [1-h] through coordinated actuation of the dry powder inhaler with each breath, and
>
> [1-i] administering to a human suffering from pulmonary hypertension with the dry powder inhaler the single event dose

> comprising at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof in 1 to 3 breaths,
>
> [1-j] wherein the human administers the entire single event dose with the dry powder inhaler in less than 5 minutes
>
> [1-k] by inhaling at least 5 micrograms of treprostinil or a pharmaceutically acceptable salt thereof per breath
>
> [1-l] by coordinating one actuation of the dry powder inhaler for each separate breath, and
>
> [1-m] wherein administration of an additional single event dose in the same manner occurs at least 3 hours later.

ECF 1-1, 18:21-57.

Claim Construction. The claim terms should be given their plain and ordinary meaning as understood by a person of ordinary skill in the art ("POSA"). *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). Here, the POSA would have a medical degree with a specialty in pulmonology or cardiology, plus at least two years' experience treating patients with PH as an attending, including with inhaled therapies, or equivalent degree or experience. Additionally, drug development as of 2006 was a team effort involving individuals with different types of expertise, including those with backgrounds in chemistry, medical device development, biostatistics, pharmacokinetics, formulation, and clinicians. Therefore, a POSA working in drug development would be part of a multi-disciplinary team. Nathan Decl. ¶¶26-27.

1. UTC will prove direct infringement.

When patients and healthcare providers use Yutrepia™ according to its proposed label, they will directly infringe claims 1-3 and 8.[2]

a. Independent Claim 1

Using Yutrepia™ according to Liquidia's proposed label will infringe claim 1, which recites a "method of treating pulmonary hypertension." ECF 1-1, 18:21-22 ([1-a]). Liquidia instructs patients to use Yutrepia™ "for the treatment of pulmonary arterial hypertension" and "pulmonary hypertension associated with interstitial lung disease." ECF 1-2 (Yutrepia™ Label), 2.

Yutrepia™'s DPI satisfies the device limitations of claim 1. Claim 1 recites "providing an inhalation device" for treating a human suffering from pulmonary hypertension where the inhalation device for treating pulmonary hypertension comprises (1) "a powder formulation of treprostinil or a pharmaceutically acceptable salt thereof" and (2) "a dry powder inhaler configured to administer single event dose" of the powder formulation of treprostinil or a pharmaceutically acceptable salt thereof. ECF 1-1, 18:24-28 ([1-b], [1-c]). The Yutrepia™ label directs physicians and patients how to use the product. ECF 1-2, 7. Yutrepia™ includes an "inhalation device for delivery of ... inhalation powder." *Id.* The Yutrepia™ label instructs directs physicians to "[t]rain patients in the administration process" and ensure patients "use" Yutrepia™ "only with the provided inhaler." *Id.*, 1-2, 5, 15. Receiving the benefit of Yutrepia™ is therefore

[2] UTC expects to assert additional claims as the litigation proceeds.

"conditioned" on using "the provided inhaler," and physicians "establish the manner [and] timing" of the administering. *See Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1365 (Fed. Cir. 2017).

Yutrepia™ is an "inhalation powder contained in a capsule ... intended for oral inhalation;" the "inhalation powder contains ... treprostinil." ECF 1-2, 1-2, 7. The inhalation device for Yutrepia™ is a "dry powder inhaler." *Id.*, 15; ECF 1-1, 18:25-28 ([1-d]). The POSA would understand that the Yutrepia™ DPI is configured to administer a single event dose of inhalation powder, as the label states Yutrepia™ should be administered 3 to 5 times per day, with each capsule being inhaled in 2 breaths. ECF 1-2, 2; ECF 1-1, 18:31-35 ([1-f], [1-g]). The POSA would understand that "single event dose" refers to a dose delivered in a single administration, including a session that involves multiple breaths. ECF 1-1, 18:25-28 ([1-d]); Nathan Decl. ¶120. The Yutrepia™ DPI is configured to administer one capsule of inhalation powder in 2 breaths. ECF 1-2, 24, ECF 1-1, 18:31 ([1-f]). Additionally, patients must "[o]nly load and inhale 1 capsule at a time." ECF 1-2, 19. Indeed, the Delaware Court previously found that "[e]ach administration [of Yutrepia™] is a single event dose." *United Therapeutics*, 624 F. Supp. 3d at 461.

Yutrepia™ is administered at an infringing dose. Claim 1 recites that "the single event dose comprises at least 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof." ECF 1-1, 18:28-30 ([1-e]). The Yutrepia™ label describes dosages of 26.5 to 159 micrograms ("mcg") per single event dose. ECF 1-2, 2-3. Claim 1 also recites that the single event dose is "delivered in 1 to 3 breaths."

Yutrepia™ "can be delivered in 2 breaths," and Liquidia instructs patients to "[a]lways inhale each capsule 2 times." *Id.*, 2, 24; ECF 1-1, 18:25-31 ([1-d], [1-f]). Claim 1 recites that "the dry powder inhaler is configured to administer the entire single event dose in less than 5 minutes with at least 5 micrograms of treprostinil ... being inhaled per breath through coordinated actuation of the dry powder inhaler with each breath." ECF 1-1, 18:31-36 ([1-h]). Liquidia instructs patients that each capsule of Yutrepia™ "must be inhaled within 5 minutes of opening." ECF 1-2, 19.

The POSA would understand that the Yutrepia™ DPI is breath-actuated, and that the administration of each dose is coordinated between the DPI and patient's breath. Nathan Decl. ¶¶167-69. Liquidia instructs patients to "close [their] lips around the mouthpiece" and "inhale." ECF 1-2, 23. Yutrepia™ is administered through coordinated actuation of the DPI with each breath, as inhalation causes the capsule to spin and release the medicine. *Id.*

Claim 1 also recites "administering [treprostinil] to a human suffering from pulmonary hypertension" according to a method with formulation, dose, breath, and dose duration limitations identical to those analyzed above. ECF 1-1, 18:36-45 ([1-i], [1-j], [1-k], [1-l]). As shown previously, Yutrepia™ satisfies those limitations. *Supra* § I(B)(1)(a); Nathan Decl. ¶¶157-60; ECF 1-2, 1-24. Lastly, claim 1 recites "wherein administration of an additional single event dose in the same manner occurs at least 3 hours later." ECF 1-1, 18:45-47 ([1-m]). Liquidia instructs patients that Yutrepia™ "should be administered 3 to 5 times per day." ECF 1-2, 1. Liquidia further instructs patients "the minimum

recommended dosing interval [is] 4 hours." *Id.*, 2. Thus, patients and healthcare providers using Yutrepia™ according to its label and instructions for use will directly infringe claim 1.

b. Claims 2 and 3

Using Yutrepia™ will also infringe claims 2 and 3. In addition to the requirements of claim 1, claim 2 requires the administration of a third "single event dose" at least 3 hours after the second "single event dose" recited in claim 1, and claim 3 requires administration of the single event dose "several times per day." ECF 1-1, 18:48-57. Liquidia instructs patients that Yutrepia™ "should be administered 3 to 5 times per day." ECF 1-2, 1. Liquidia further instructs patients that "the minimum recommended dosing interval [is] 4 hours." *Id.*, 2. The POSA would understand "several times per day" to encompass a regimen of 3-5 doses per day. Nathan Decl. ¶¶196-98. As shown above, using Yutrepia™ comprises the administration of a single event dose of 26.5 to 159 micrograms in two breaths, which likewise satisfies the limitations of claims 2-3. *See supra* § I(B)(1)(a). Thus, patients and healthcare providers using Yutrepia™ according to Liquidia's label and instructions for use will directly infringe claims 2 and 3.

c. Claim 8

The use of Yutrepia™ will infringe claim 8, which requires a single event dose in the method of claim 1 to provide "a maximal treprostinil plasma concentration in the human of at least 0.65±0.28 ng/mL." ECF 1-1, 19:6-8. The maximum plasma concentration for a drug is typically abbreviated as C_{max}. Nathan Decl. ¶65. The

Yutrepia™ label establishes that in clinical trials, the mean C_{max} value after a dose of 79.5 mcg treprostinil was 1.48 nanograms per milliliter ("ng/mL") and proportional to the dose administered. ECF 1-2, 8. Thus, prescribed Yutrepia™ doses cause patients to experience C_{max} of at least 0.65±0.28 ng/mL (*i.e.*, 0.37-0.93). Liquidia's clinical trials further demonstrate that mean C_{max} for single event doses of 25 to 150 mcg Yutrepia™ ranged from 0.31-1.25 ng/mL. Exhibit 18 (Roscigno 2020a), Table 3; *see also* Exhibit 20 (Roscigno 2020b); Nathan Decl. ¶206. For example, patients taking a single event dose of 25 mcg experienced C_{max} of 0.19-0.54 ng/mL, and thus experienced C_{max} of at least 0.65±0.28 ng/mL. Exhibit 18, Table 3. Patients taking 50 mcg experienced mean C_{max} of 0.45 ng/mL, also at least 0.65±0.28 ng/mL, as claimed. *Id.* Thus, using Yutrepia™ according to Liquidia's label will directly infringe claim 8.

2. UTC will prove that Liquidia is intentionally inducing infringement of the '782 patent.

In the context of induced infringement, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [the accused infringer's] affirmative intent to induce infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) Moreover, "the decision to continue seeking FDA approval of [infringing] instructions may be sufficient evidence of specific intent to induce infringement." *Lilly*, 845 F.3d at 1368. A drug label providing instructions "that will cause at least some users to infringe the asserted method claims" demonstrates specific intent to induce infringement. *AstraZeneca*, 633 F.3d at 1060.

Liquidia will induce infringement of claims 1-3 and 8 of the '782 patent because it plans to market Yutrepia™ with a label that expressly directs physicians and patients to use the product in an infringing manner. Liquidia's Yutrepia™ label instructs users to infringe the asserted method claims. *Supra* § I(B)(1). Moreover, Liquidia is aware of the '782 patent, and has nevertheless intentionally proceeded to seek FDA approval for a label that will instruct infringement, showing that Liquidia specifically intends to induce infringement.[3] *Id.*; Nathan Decl. ¶¶214-217. Thus, UTC will likely prove induced infringement.

C. There Is No Substantial Question Regarding Validity

The '782 patent enjoys a presumption of validity sufficient to satisfy UTC's burden to show success on the merits regarding validity. "Every patent is presumed valid, so if [the infringer] fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies [the patentee's] burden on validity" at the preliminary injunction stage and throughout the litigation. *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001) (affirming preliminary injunction); *see BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1399 (Fed. Cir. 2022); *Natera, Inc. v. Neogenomics Lab'ys, Inc.*, 2023 WL 11852796, at *2, 4 (M.D.N.C. Dec. 27, 2023), *aff'd*, 106 F.4th 1369 (Fed. Cir. 2024). The presumption that patents are valid "is never annihilated, destroyed, or even weakened, regardless of what facts are of record." *ACS Hospital Sys., Inc. v.*

[3] An infringer's belief that a patent is invalid is not a defense to infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 647 (2015).

Montefiore Hospital, 732 F.2d 1572, 1574-75 (Fed. Cir. 1984); 35 U.S.C. § 282. Liquidia bears the burden of coming forward with evidence of invalidity.

In the '793 IPR, the PTAB found that the '793 patent was unpatentable as obvious over certain documents allegedly in the prior art. Those references, and Liquidia's arguments from that proceeding, were expressly brought to the Patent Office's attention during prosecution of the '782 patent. Exhibit 15, 3-17, 32, 33-40. After reviewing that evidence and Liquidia's arguments, the Patent Examiner concluded that the claims were patentable and issued the '782 patent. *Id.* at 48-49. Nothing about the '793 IPR disrupts the presumption of validity that each claim of the '782 patent enjoys. *Microsoft*, 564 U.S. at 109 (challenger always bears a clear-and-convincing-evidence burden on invalidity). Accordingly, UTC is likely to prevail on the merits.

II. UTC Will Suffer Imminent Irreparable Harm if a TRO Is Not Entered

Liquidia's infringing launch of Yutrepia™ for PAH and PH-ILD will result in immediate irreparable harm to UTC that "no damages payment ... could address." *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). "It is well-settled that, because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." *Hybritech Inc. v. Abbott Lab'ys*, 849 F.2d 1446, 1456-57 (Fed. Cir. 1988).

Irreparable harm notably includes not only unquantifiable harms, such as lost goodwill and first mover advantages, but also difficult-to-quantify financial harms like

price erosion and lost sales. *See, e.g.*, *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017) (affirming irreparable harm findings based on lost sales, price erosion, and direct competition); *Banilla Games, Inc. v. Asmita Enter. LLC*, 2023 WL 3681697, at *8 (E.D. Va. Feb. 28, 2023) ("Courts in the Fourth Circuit have repeatedly recognized that the threat of a permanent loss of customers and the potential loss of goodwill support a finding of irreparable harm." (quotation marks omitted)). Moreover, even if some "competitive harms theoretically can be offset by monetary payments," Liquidia "likely will be faced with a substantial damages award" and "may be unable to pay," thereby making UTC's injury irreparable. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155-56 (Fed. Cir. 2011). In addition to violating UTC's right to exclude, Liquidia's launch will cause UTC irreparable harm in multiple other ways.

First, Liquidia's entry in the PAH and PH-ILD markets is imminent, as there are now "no legal barriers" in its way, Exhibit 21, 4, and such entry would cause immediate and lasting price erosion to UTC's Tyvaso® products. Selck Decl. ¶¶68-81. When more than one similarly situated drug is available to treat a condition, manufacturers must compete for inclusion and positioning on insurance coverage formulary lists. *Id.*, ¶¶52-55.

[redacted] UTC's Associate Vice President of Market Access [redacted]

[redacted] Exhibit 19 (Barton Tr.) at 26:6-27:3, 79:6-18; 138:16-141:22.

If Yutrepia™ launches, insurance companies and other payors will demand that UTC lower its prices to compete for formulary inclusion and placement; otherwise, certain payors would exclude UTC's products from coverage that Liquidia admits is critical for patient access. Selck Decl. ¶ 75. Even if Yutrepia™ "were later removed from the market, [the] at-risk launch also would cause [UTC] to suffer loss of reputation and goodwill should [UTC] attempt to recapture the higher prices eroded by" Yutrepia™'s launch. *In re Aflibercept Patent Litig.*, 2024 WL 3422971, at *49 (N.D.W. Va. June 24, 2024); *Celsis*, 664 F.3d at 930 (affirming PI based on "loss of customer goodwill (*e.g.*, when an effort is later made to restore the original price)."). Here, given the complex and "sticky" nature of the pharmaceutical market, price erosion would likely be irreversible. Selck Decl. ¶80. Yutrepia™'s launch will result in payors demanding that UTC offer additional rebates or a lower effective price—price concessions that UTC practically could not walk back, at least not without material reputational harm.

Second, even if UTC lowers its prices, Liquidia's launch will erode sales and market share for UTC's Tyvaso® products, making it "impossible to restore [UTC]'s … exclusive position by an award of damages and a permanent injunction." *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996); Selck Decl. ¶¶91-97. If launched, Yutrepia™ would directly compete with UTC's Tyvaso® products at eroded prices. Selck Decl. ¶¶63-67. Such "[d]irect competition in the same market ... strongly" suggests the

existence of irreparable harm. *See, e.g.*, *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012). Liquidia has made clear that it intends to offer additional discounts to secure market access and announced its intention to transition patients from UTC's products to its forthcoming product upon final approval. ECF 1-5, 5:6-16, Exhibit 21, 11-12. [redacted] Selck Decl. ¶70. [redacted] *Id.*, ¶¶70, 91, 93. UTC's products would be effectively unavailable to all patients diagnosed with PAH and PH-ILD who are covered by that formulary, pushing UTC out of major segments of the market. *Id.*, ¶¶91-93.

Because payors and physicians are likely to view the two products as highly similar clinical alternatives, permitting Yutrepia™'s infringing launch would also likely commoditize dry powder treprostinil products and reduce UTC's first mover advantage, significantly eroding UTC's market share, sales, and brand recognition. Selck Decl. ¶¶110-13. Even if Yutrepia™ were later enjoined, the injury would still be irreparable "because market share is so difficult to recover." *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, 2016 WL 5348866, at *13 (D.N.J. Sept. 23, 2016); *see Natera*, 2023 WL 11852796, at *7. Improper early access to the market would also give Liquidia a head start upon re-launch and increase its impact on future prescriber decisions that would not "ever be properly

captured through money damages only." *Lonza Walkersville, Inc. v. Adva Biotech. Ltd.*, 581 F. Supp. 3d 736, 750 (D. Md. 2022).

UTC is also expending significant resources to educate physicians on how to diagnose PH-ILD patients and thereby grow the untapped PH-ILD market; but if Yutrepia™ launches, UTC will be forced to choose between (a) continuing those efforts, despite that they will lead to some amount of improper Yutrepia™ sales, or (b) stopping its market expansion efforts altogether. Selck Decl. ¶¶110-13. These Hobson's choices pose actual and imminent irreparable harms to UTC that can only be fully addressed with a TRO and PI.

Third, Liquidia's launch will cause UTC to suffer irreparable harm due to "loss of goodwill [and] damage to reputation." *See Fresenius*, 2016 WL 5348866, at *13. UTC has spent significant resources building its Tyvaso® brand, and Liquidia is attempting to freeride on that goodwill by prematurely marketing a competing product that would inalterably impact UTC's market reputation. Selck Decl. ¶¶114-16. Worse, an injunction withdrawing Yutrepia™ from the market could cause backlash among patients who have become accustomed to taking Yutrepia™, even though all those patients could take Tyvaso®. *Id.* Under those circumstances, UTC would "suffer reputational harms" just for enforcing its valid patent rights; such harm is irreparable and favors an injunction. *Aflibercept*, 2024 WL 3422971, at *42-*43.

Fourth, even if some of UTC's damages were quantifiable, Liquidia would likely be unable to pay UTC's potential monetary damages. Selck Decl. ¶¶153-58. Liquidia

operates at a significant net loss; even if it were to start generating revenue, an understated estimate of UTC's monetary damages, including from price erosion and lost sales, would be significantly higher than Liquidia's potential revenue—especially since Liquidia would be selling at eroded prices. *Id*. As Liquidia "may be unable to pay" UTC's damages, the injury to UTC—even if quantifiable—would be irreparable. *Robert*, 659 F.3d at 1155-56.

Finally, there is no doubt that there is "some connection" between the harm alleged and the infringing acts. *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1364 (Fed. Cir. 2013). The '782 patent is a method patent, and any Yutrepia™ launch will infringe the methods described. *See supra* § I; *see Natera*, 2023 WL 11852796, at *8 (finding causal nexus in method patent case); Exhibit 21, 11-12.

III. The Balancing of Hardships Favors UTC

Unless Liquidia is enjoined from launching Yutrepia™, UTC will suffer severe and irreversible harm that outweighs any potential hardship to Liquidia from maintaining the status quo for a few short weeks while this Court considers the PI Motion. A preliminary injunction is appropriate where, as here, the patent owner "would lose the value of its patent, while [the accused infringer] would only lose the ability to go on to the market and begin earning profits earlier." *Glaxo Grp. Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003). UTC has undertaken significant and costly efforts to research, develop, patent, and commercialize Tyvaso® products and develop the relevant market, and its billions-of-dollars spent on research and development from 2017-2022 outstrips Liquidia's by at least

an order of magnitude. Selck Decl. ¶¶161-68. If Yutrepia™ were allowed to launch, UTC may never restore its market share, pricing, reputation, or goodwill. *Supra* § II.

In contrast, any harm Liquidia might suffer from the TRO would be minimal. Liquidia has not launched yet, and any harm to Liquidia would be in effect only until UTC's PI Motion is resolved, and that limited harm is not sufficient to justify denying this motion. *Aflibercept*, 2024 WL 3423047, at *56 ("The harm from a patentee's loss of the value of its patent is more substantial than the harm from an accused infringer's inability to enter the market earlier."). Moreover, Liquidia's actions in seeking FDA approval mitigate against a finding of harm if enjoined. Liquidia had a choice: it could carry its own burden and prove the safety and efficacy of its proposed product or it could freeride on UTC's clinical development to reduce costs and speed approval. Liquidia chose the latter. *Supra* at 3-6. Indeed, not only did Liquidia forgo conducting its own trials, it also hired UTC employees, reducing costs and speeding up Liquidia's own development timeline for Yutrepia™. Liquidia cannot now claim hardship from having to contend with UTC's patent rights—based on years of costly research and development—when it made the conscious decision to piggyback on UTC efforts. "[T]he balance of hardships tip[s] in [UTC]'s favor" because Liquidia's "harms [a]re almost entirely preventable and [a]re the result of its own calculated risk to launch its product pre-judgment." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (quotation marks omitted). The harm to UTC if Liquidia pre-emptively launches prior to the resolution of UTC's claims is irreversible. *Supra* § II. Liquidia's inequitable actions further suggest "a balancing of the

equities would lie in [UTC]'s favor." *Grier v. Gallagher*, 2014 WL 4682083, at *3 (W.D.N.C. Sept. 19, 2014).

IV. The Public Interest Favors Granting a TRO and Preliminary Injunction

The public interest favors resolving UTC's Motion prior to Liquidia's infringing launch. "[T]he public interest nearly always weighs in favor of protecting property rights," including UTC's '782 patent—especially during the few short weeks necessary for this Court to adjudicate UTC's PI Motion. *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 647 (Fed. Cir. 2015). The compelling public interest in encouraging investment and innovation in drug development outweighs "a general interest in access to lower-cost drug products" via an infringing, cheaper alternative. *Aflibercept*, 2024 WL 3422971, at *51. UTC has been a leader in developing innovative therapies to treat PH, including Tyvaso DPI®, and patent rights are essential to preserving such investments. Selck Decl. ¶¶161-68, 183. Importantly, if a TRO is entered, PAH and PH-ILD patients will continue to have access to a wide variety of treatments, including both dry powder and nebulized treprostinil treatments. *Id.* ¶¶174-78. Moreover, UTC has ample capacity to meet the demands of the market, so no patient will be left without the medicine they need if Liquidia is temporarily enjoined from entering the market. *Id.* Accordingly, the public interest also favors the injunction.

CONCLUSION

For the foregoing reasons, UTC respectfully requests that the Court grant UTC's Motion for a Temporary Restraining Order[4] and enter the Proposed Order.

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[4] UTC is prepared to post a reasonable bond, and requests a hearing to determine the amount of the bond to the extent the Court determines one is necessary.

This the 9th day of May, 2025.

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CERTIFICATE OF WORD COUNT

The undersigned certifies that this brief is in compliance with Rule 7.3(d)(1) of the Local Rules for the Middle District of North Carolina, in that it contains less than 6,250 words, excluding the portions of the brief covered by Local Rule 7.3(d).

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed with the Court using the CM/ECF system. I further hereby certify the foregoing documents are being served with the Complaint and accompanying documents via a designated delivery service pursuant to 26 U.S.C. § 7502(f)(2) addressed as follows:

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